REMARKS

A. Status of the Claims

Claims 42-85 are withdrawn from consideration. Currently, claims 40, 41, 87-90, 139 and 140 are under examination and stand rejected as follows:

(1) Claims 40, 41, 139 and 140 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over international application number WO 96/11712 to Kayyem et al. ("Kayyem"), in view of U.S. Patent No. 7,008,924 to Yan et al. ("Yan"), U.S. Patent No. 5,989,545 to Foster et al. ("Foster"), and an article by Kabanov et al. titled "Interpolyelectrolyte and Block Ionomer Complexes for Gene Delivery: Physicochemical Aspects," Adv. Drug Delivery Rev. 30: 49-60 (1998) ("Kabanov");

(2) Claims 40, 41, 87-90, 139 and 140 are provisionally rejected on the ground of nonstatutory double patenting as being allegedly unpatentable over claims 1, 7-24, 30, 31, 33-50, 57 and 59-61 of co-pending Application No. 10/591,486 ("the '486 application");

(3) Claims 40, 41, 87-89, 139, and 140 are provisionally rejected on the ground of nonstatutory double patenting as being allegedly unpatentable over claims 1, 7-15, 29, 68-77, and 241-249 co-pending Application No. 10/793,138 ("the '138 Application"); and

(4) Claims 40, 41, 87-90, 139, and 140 are provisionally rejected on the ground of nonstatutory double patenting as being allegedly unpatentable over claims 1, 10-24, 30, 31, 33-50, 57, 59-61, and 63-66 of co-pending Application No. 11/073,307 ("the '307 Application").

B. Explanation of the Amendments

In this paper, Applicants have corrected a minor grammatical error in claim 40. This amendment was not made for any reason related to patentability and does not introduce any new matter.

C. Applicants' Claims Are Patentable Over Kayyem, in view of Yan, Foster, and Kabanov

Applicants respectfully traverse the rejection of claims 40, 41, 139 and 140 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Kayyem, in view of Yan, Foster, and Kabanov. Briefly, the traversal is based on the following grounds: (1) both Kayyem and Foster teach away from the proposed combination of references, and (2) the Office Action's proposed combination of references renders Kayyem unsuitable for its intended purpose. For at least these reasons, the rejection under 35 U.S.C. § 103(a) should be withdrawn.

1. Kayyem and Foster Teach Away From the Proposed Combination of References

Independent claim 40, as amended, reads as follows:

> 40. A composition comprising a non-covalent association complex of:
>
> a positively charged backbone covalently attached to a plurality of amino acid sequences, wherein said amino acid sequences are selected from the group consisting of $(gly)_p$-RGRDDRRQRRR-$(gly)_q$ (SEQ ID NO:19), and $(gly)_p$-YGRKKRRQRRR-$(gly)_q$ (SEQ ID NO: 20) wherein p and q are each independently an integer of from 0 to 20;
>
> a negatively charged backbone having a plurality of attached targeting agents; and
>
> a negatively charged backbone having a plurality of attached biological agents, wherein each of said biological agents is a therapeutic agent or a cosmeceutical agent and not a nucleic acid;
>
> wherein said non-covalent association complex carries a net positive charge.

The Office Action attempts to arrive at the claimed invention by combining Kayyem, Foster, Yan, and Kabanov. However, the proposed combination of references is improper, because Kayyem and Foster actually teach away from the proposed combination. To see why this is so, consider Yan, which is directed to the use of HIV-TAT protein transduction

domains, such as the amino acid sequence Y-G-R-K-K-R-R-Q-R-R-R, for internalizing proteins into cells. [See Yan, col. 35, lines 23-32]. Yan reports that HIV-TAT protein transduction domains deliver proteins non-selectively to a variety of different cell types, including liver, kidney, lung, heart, and brain tissue:

> In these procedures, FITC-constructs (FITC-labeled G-G-G-G-Y-G-R-K-K-R-R-Q-R-R-R; SEQ ID NO: 12), which penetrate tissues following intraperitoneal administration, are prepared, and the binding of such constructs to cells is detected by fluorescence-activated cell sorting (FACS) analysis. Cells treated with a tat β-gal fusion protein will demonstrate β-gal activity. Following injection, expression of such a construct can be detected in a number of tissues, including liver, kidney, lung, heart, and brain tissue. [Yan, col. 35, lines 32-41 (emphasis added)].

Because Yan reports that its use of HIV-TAT protein transduction domains results in successful delivery of tat β-gal fusion protein to various tissues, including liver, kidney, lung, heart, and brain tissue, it is clear that the delivery of Yan's constructs is not cell-specific, but instead is non-selective with respect to cells of numerous tissue types.

In direct contrast, both Kayyem and Foster require cell-specific delivery. For instance, the specification of Kayyem explicitly requires that its delivery vehicles be cell-specific:

> [t]he present invention provides delivery vehicles and methods for the delivery of physiological agents, including contrast agents and therapeutic agents, to a cell. The delivery vehicles comprise two or more polymeric molecules, a cell targeting moiety, and a physiological agent. Accordingly, the delivery vehicles are targeted to a certain cell type, depending on the targeting moiety used, and then generally are taken up by the target cells. The physiological agent is thus targeted to a specific cell type. [Kayyem, p. 7, lines 2-8].

Similarly, Foster's agents, which are for "inhibit[ing] the release of at least one neurotransmitter or neuromodulator or both from the synaptic terminals of nociceptive afferents," [Foster, col. 6, lines 5-7], are also cell-specific, particularly to nociceptive afferent neurons. In fact, Foster states that its agents must include a "targeting moiety" (abbreviated "TM") and that "[t]he TM provides specificity for the BS [i.e., binding site] on the nociceptive afferent neuron." [Foster, col. 7, lines 1-2, and 15-17].

Thus, whereas Yan reports non-selective delivery of proteins using HIV-TAT protein transduction domains, both Kayyem and Foster required cell-specific, selective delivery of their biological agents. Accordingly, both Kayyem and Foster teach away from the use of HIV-TAT protein transduction domains, which, according to Yan, do not lead to cell-specific, selective delivery of biological agents.

For at least this reason, the proposed combination of references is improper and the rejection of claims 40, 41, 139 and 140 under 35 U.S.C. §103(a) should be withdrawn.

2. The Office Action's Proposed Combination Of References Renders The Delivery Vehicles of Kayyem Unsuitable for Their Intended Purpose

As noted above, Kayyem requires its delivery vehicles to be cell-specific. The Office Action's proposal to use Yan's HIV-TAT protein transduction domains in Kayyem's delivery vehicles would be expected to render the delivery vehicles of Kayyem unsuitable for their intended purpose, because Yan reports that using the HIV-TAT protein transduction domains results in non-selective delivery of biological agents. Accordingly, the rejection is improper and should be withdrawn. See In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (holding that a claimed blood filter assembly was not obvious over a prior art device

because the proposed modification of the prior art device would render it unsuitable for its intended purpose).

D. Double Patent Rejections

Applicants respectfully request that this provisional rejections set forth on page 11 of this paper be held in abeyance until the other rejections in this case are overcome and the claims of this case are otherwise in condition for allowance. Applicants reserve the right to file a terminal disclaimer in the event that it is deemed necessary in a later stage of prosecution.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-3732**, Order No. 13720-105065US1.

Respectfully submitted,
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